

Whitehall-Robins
Five Giralda Farms
Madison, NJ 07940-0871
Telephone (973) 660-5500
Website address: http://healthfront.com

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January 19, 2000

# Centrum®Focused Formulas™Mental Clarity

## Notification of Statements on Dietary Supplement Labels

Elizabeth A. Yetley, Ph.D., R.D., Director Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 C Street, SW Washington, D.C. 20204

Dear Dr. Yetley:

Reference is made to Centrum Focused Formulas, marketed by Whitehall-Robins Healthcare, ("Whitehall-Robins"), and a division of American Home Products Corporation.

Pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, as codified in 21 U.S.C. §343(r)(6), notification is submitted for structure/function statements made on the following dietary supplement product.

**Product Name:** 

Centrum Focused Formulas

Mental Clarity

Ingredients:

Vitamin E, Thiamin, Riboflavin, Niacin, Vitamin B6,

Folic Acid, Vitamin B12, Pantothenic Acid, Zinc, Ginkgo Biloba,

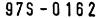
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Company Name/

Whitehall-Robins Healthcare

Address: Five Giralda Farms

Madison, NJ 07940-0871



#### **Statements on the Carton Label:**

- 1. Front Panel/ Top Flap
  - A blend of select nutrients for a specific health need\*
  - Helps supply energy to the brain and supports normal alertness and concentration\*

### 2. Back Panel

Centrum developed this advanced formula using ingredients which may:

- Help maintain normal memory and concentration\*
- Assist circulation of blood to the brain\*
- Help maintain normal mental alertness\*

#### What are Centrum Focused Formulas?

- Centrum Focused Formulas are advanced combinations of vitamins, minerals, herbals, or other nutrients shown in scientific research to support a specific health area. \*
- Centrum Focused Formulas are designed to provide nutritional solutions to help you better address your specific health needs. \*

In accord with 21 CFR §101.93, the disclaimer statement is bolded and boxed on all panels of the carton label where structure/function claims appear.

The undersigned certifies that the information contained in this notice is complete and accurate, and that Whitehall-Robins has substantiation that the statements made are truthful and not misleading.

As required, the original and two copies of this notification are enclosed. If you have any questions regarding this information, please contact the undersigned at (973) 660-5751.

Sincerely,

WHITEHALL-ROBINS HEALTHCARE

Eleanor F. Barbo Senior Director Regulatory Affairs